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7590

02/17/2004

Barry E. Sammons
Quarles & Brady, LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202

EXAMINER

FETZNER, TIFFANY A

ART UNIT

PAPER NUMBER

2859

DATE MAILED: 02/17/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,527	12/10/2001	Kiaran McGee	630666.90831	7662

TITLE OF INVENTION: MAGNETIC RESONANCE IMAGING OF PROSTATE BRACHYTHERAPY SEEDS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1330	\$300	\$1630	05/17/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHT THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPO PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THE STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is not claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issued on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is the patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail

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CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 02/17/2004

Barry E. Sammons
Quarles & Brady, LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202

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(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	\$1330	\$300	\$1630	05/17/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
FETZNER, TIFFANY A	2859	324-309000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

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- ☐ A check in the amount of the fee(s) is enclosed.
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- ☐ The Director is hereby authorized to charge the required fee(s), or credit any overpayment Deposit Account Number _____ (enclose an extra copy of this form).

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(Authorized Signature)

(Date)

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.**

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FETZNER, TIFFANY A

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2859

DATE MAILED: 02/17/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 34 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 34 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability	Application No.	Applicant(s)	
	10/016,527	MCGEE ET AL.	
	Examiner	Art Unit	
	Tiffany A Fetzner	2859	<i>RF</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/30/2003.
2. ☒ The allowed claim(s) is/are 1-4,6-14,16,17 and 19.
3. ☒ The drawings filed on 12/10/2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Examiner's comment

1. The examiner has reviewed applicant's After-final amendment of December 30th 2003, and considers it to be free of new matter and acceptable for entry into the application. The following action is based on the applicant's December 30th 2003 After-final amendment as entered.

Response to Arguments

2. Applicant's arguments, see page 7 paragraph 4 through page 9 paragraph 3, filed December 30th 2003, with respect to the **Frankel** and **Bernstein '418** reference have been fully considered and are persuasive. The rejections of October 8th 2003 have been withdrawn.

3. The examiner no longer considers the **Frankel** and **Bernstein '418** references to be prior art against the after-final amended claims of the instant application.

4. The examiner agrees with the applicant's after-final amendment arguments of December 30th 2003 that:

A) Frankel "discloses three different pulse sequences ("Sequence 1", "Sequence 2", and "Sequence 3") which can be used to acquire an image of the breast. **Frankel** teaches the acquisition of a single k-space data set and the reconstruction of a single magnitude image and a single phase image (not a phase difference image) from this k-space data set. Regardless of which one of three sequences is chosen, only one pulse sequence is used and only one k-space data set is acquired with the selected pulse sequence. Differentiation between tissue types is achieved in the reconstructed magnitude image by judicious selection of scan parameters such as TR, TE and flip angle. In addition, differentiation between tissues and a silicon implant can be seen in a phase image reconstructed from the same data." [See the December 30th 2003 After final amendment remarks page 7 paragraph 4 through page 8 paragraph 1]

5. The examiner also agrees with the applicant's after-final amendment arguments of December 30th 2003 that:

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B) This reference (i.e. **Frankel**) "does not teach acquiring two k-space data sets using two different pulse sequences, and it does not disclose producing a phase difference image between two acquired k-space data sets of any kind.

C) This reference" (i.e. **Frankel**) "does teach a method for producing an MR image in which a silicon implant in a breast can be differentiated. Applicant's invention also produces an MR image in which implanted devices can be differentiated from surrounding tissues. But the two methods are different. With applicant's method an additional k-space data set must be acquired using a pulse sequence that different from that used to acquire the first k-space data set. In addition, a phase difference image is produced from these two data sets, not just a phase image of one of them.

D) The Bernstein '448 patent teaches a method for producing an angiogram using an MRI system. This field is referred to as MR angiography or MRA. The object of MRA is to visualize the vasculature of the subject and null from the image all other structures. MRA does this by acquiring two data sets and effectively subtracting the two resulting images to null out static structures. Such nulled static structures include tissues (other than moving blood) and stationary implants. In other words, one would not see a stationary implant in the MRA image produced according to Bernstein .418. This is totally incompatible with the objectives set forth in the **Frankel** reference and this fact is clear *objective evidence* that it would not be obvious to one skilled in this art to combine **Bernstein '418** with the **Frankel** reference." [See the December 30th 2003 After final amendment remarks page 8 under the equations through page 9 paragraph 1]

6. The examiner additionally agrees with the applicant's after-final amendment arguments of December 30th 2003 that:

E) "The MRA method in **Bernstein '418** is a variant of the so-called phase contrast (PCMRA) method. This is an alternative to the contrast enhanced method (CEMRA). In **Bernstein** the two image data sets are acquired with me exact same pulse sequence except a velocity encoding gradient is used in both sequences (See Figs. 38 and 3C) and this velocity encoding gradient is flipped in polarity in one of them. The two pulse sequences must be the same because you want the stationary tissues and structures to appear the same in both images so they null out when the difference is calculated (complex difference in this variation of the PCMRA method). **Bernstein** does not disclose the use of a pulse sequence "suitable for imaging stationary spins" as specifically required by" (i.e. after-final amended) "claim 1, and it does not disclose or suggest acquiring two k-space data sets with a spin-echo pulse sequence and a gradient-recalled echo pulse sequence as specifically required in **Independent claims 8 and 19**.

F) The **Bernstein '448** is not pertinent to the present invention. Its teachings are totally incompatible with the objective of the present invention. That is, **Bernstein** teaches the reconstruction of an image in which stationary tissues and stationary implants are nulled out of t e image so that only the blood carrying vasculature is seen."

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[See the December 30th 2003 After final amendment remarks page 9 paragraphs 2 through 3].

Canceled claims

7. **Claim 5 is canceled** as per applicant's July 16th 2003 amendment response.

8. **Claims 15 and 18 are canceled** as per applicant's December 30th 2003 After-final amendment which has been marked okay to enter by the examiner.

9. The following is an examiner's statement of **Reasons for Allowance**:

10. With respect to **Twice Amended Independent Claim 1**, "A method for producing an image of a subject with a magnetic resonance imaging (MRI) system which **enables a previously implanted device to be located**, the steps comprising:

a) acquiring a first k-space data set with the MRI system using a first pulse sequence **suitable for imaging stationary spins**;

b) acquiring a second k-space data set with the MRI system using a second pulse sequence **suitable for imaging stationary spins** which is different from the first pulse sequence;

c) reconstructing first and second complex **MR** images of the subject from the respective first and second k-space data sets;

d) [e)] calculating a magnitude **MR** image from either one of said first or second complex **MR** images reconstructed in step c); and

e) [d)] calculating a phase difference **MR** image [~~from~~] between the first and second complex **MR** images of step c);

f) employing the phase difference MR image of step e); to locate the implant in the subject; and g) displaying the location of the implant from step f); in the magnitude MR image from step d)."

11. With respect to **twice Amended Independent Claim 8**, "A method for producing an image of tissues containing an implant with a magnetic resonance imaging (MRI) system the steps comprising:

a) acquiring first and second k-space data sets with the MRI system by performing a series of pulse sequences which acquire a set of NMR spin echo signals for the first k-space data set and a set of gradient-recalled echo signals for the second k-space data set;

b) reconstructing first and second complex **MR** images of the tissues containing the implant from the respective first and second k-space data sets;

c) calculating a phase difference **MR** image [~~from~~] between the first and second complex **MR** images;

d) calculating a magnitude **MR** image using data from either said first or second complex **MR** images; and

e) employing the phase difference **MR** image of step c); to display the location of the implant in the magnitude **MR** image of step d) and [~~to~~] form the image."

12. With respect to **Amended claim 19**, "A method for producing an image of a subject with a magnetic resonance imaging (MRI) system which differentiates between soft tissues and which differentiates between tissues and a device, the steps comprising:

- a) acquiring a first k-space data set with the MRI system using a spin-echo pulse sequence;
- b) acquiring a second k-space data set with the MRI system using a gradient-recalled echo pulse sequence;
- c) reconstructing first and second complex **MR** images of the subject from the respective first and second k-space data sets;
- d) calculating a phase difference **MR** image [~~from~~] **between** the first and second complex images which differentiates between tissues and the device;
- e) calculating a magnitude **MR** image from **either** one of said first or second complex **MR** images which differentiates between tissues; and
- f) combining the phase difference **MR** image **of step d)**; with the magnitude **MR** image **of step e)** to form the image of the subject."

13. These amended claims are considered to be allowable over the prior art because each of these claims contain novel and non-obvious combinational steps [i.e., in **after-final amended claim 1**, limitations **a)** through **g)**; in **after-final amended claim 8**, limitations **a)** through **e)**; in **after-final amended claim 19**, limitations **a)** through **f)**]; It is the combination of these steps taken in conjunction with one another that is the feature of novelty in each of applicant's independent claims, and it is this feature that distinguishes applicant's application from the prior art.

14. The prior arts of record, **Bernstein et al.**, **Frankel et al.**, **Moerland et al.**, **Tominaga et al.**, **Slater et al.**, **Darrow et al.**, **Harvey**, **Sliwa et al.**, and **Zhang et al.**,

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etc., do not teach, suggest, or show the combination set of method steps set forth in applicant's **after-final amended claims 1, 8, and 19**. It would not have been obvious to one of ordinary skill in the art, at the time that the invention was made to perform each of the steps as set forth by applicant because applicant's amended independent claims require/comprise: that two different k-space data sets be acquired, with two different pulse sequences, which result in two different MR complex images; calculating a phase difference between the resulting complex images, a magnitude image from one of the complex images, and the use of both the magnitude image and the phase difference to produce an MR image which locates an implant/device within a subject. [See **after-final amended claims 1, 8, and 19**] These combinational features teach away from what is known in the art. [See the arguments provided by applicant, in the response to arguments section of this action, above, for why the **Bernstein et al.**, patent and the **Frankel et al.**, article are no longer considered prior art by the examiner.] Therefore, applicant's method is considered to be both novel and nonobvious by the examiner.

15. With respect to dependent **claims 2-4, 6, and 7**, which depend from **amended independent claim 1**, and **dependent claims 9-14, 16, and 17**, which depend from **amended independent claim 8**, each of these claims are considered to be allowable by the examiner because they depend from an allowable independent claim, therefore the same reasons for allowance, novelty and nonobviousness, that apply to **amended independent claims 1, and 8** also apply to **Dependent claims 2-4, 6, 7, 9-14, 16, and 17**, and need not be reiterated.

16. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

17. The **prior art made of record** and not relied upon is considered pertinent to applicant's disclosure.

A) **Darrow et al.**, US patent 5,730,129 which shows another MRI tracking system for locating an interventional device within a patient, superimposed on a graphical display.

B) **Harvey** US patent 6,275,038 B1 which shows additional phase-difference techniques used with MRI.

C) **Sliwa et al.**, US patent 6,368,275 B1 issued April 9th 2002 with an effective date of October 7th 1999.

D) **Zhang et al** reference US patent 6,332,088 B1 issued December 18th 2001 with an effective date of November 12th 1998.

E) **Bernstein et al.**, US patent 5,226,418 issued July 1993 which shows three pulse sequences, a phase difference image and a magnitude image but fails to teach or suggest the method steps as taught by applicant. [See the response to arguments above.]

F) **Frankel et al.**, article "Characteristics of magnetic resonance sequences used for imaging silicone gel, saline, and gel-saline implants at low field strengths"; Investigative

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radiology (UNITED STATES) **Aug 1994**, 29 (8) p781-6, ISSN 0020-9996 Journal

Code: 0045377

G) Moerland et al., article. (i.e. article by **Moerland M A; Wijrdeman H K;**

Beersma R; Bakker C J; Battermann J J International journal of radiation oncology,

biology, physics (UNITED STATES) **Mar 1 1997**, 37 (4) p927-33, ISSN 0360-3016

Journal Code: 7603616).

H) Tominaga et al., article (i.e. "Magnetic resonance imaging of titanium anterior cervical spine plating systems" **Tominaga T.**; Shimizu H.; Kosu K.; Kayama T.;

Yoshimoto T.; Cooper P.R.; Sonntag V.K.H. Neurosurgery (NEUROSURGERY) (United States) **1995**, 36/5 (951-955) CODEN: NRSRD ISSN: 0148-396X).

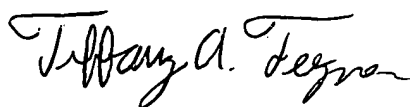
G) Slater et al., US patent 6,200,258 B1 issued March 13th 2001.

Conclusion


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany Fetzner whose telephone number is: (571) 272-2241. The examiner can normally be reached on Monday-Thursday from 7:00am to 4:30pm., and on alternate Friday's from 7:00am to 3:30pm.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez, can be reached on (571) 272-2245. The **only official fax phone number** for the organization where this application or proceeding is assigned is **(703) 872-9306**.

20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0956.



TAF
February 10, 2004



Diego Gutierrez
Supervisory Patent Examiner
Technology Center 2800

EDWARD LEFKOWITZ
PATENT EXAMINER
FEB 10 2004